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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|------------------------------|----------------------|---------------------|------------------|
| 10/551,056 | 02/07/2007 | Yuval Shezifi | 0516US-Expandis | 6365 |
| | 7590 07/29/200 NNOVATIONS | EXAMINER | | |
| 30 FERN LANE | | | SCHNEIDER, LYNNSY M | |
| SOUTH PORTLAND, ME 04106 | | | ART UNIT | PAPER NUMBER |
| | | | 3733 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 07/29/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
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| | 10/551,056 | SHEZIFI ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | LYNNSY SCHNEIDER | 3733 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | | |
| | / IC CET TO EVOIDE AMONTH! | C) OD TUUDTY (20) DAVC | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | lely filed the mailing date of this communication. (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>07 Ju</u> | ine 2009 | | | | | |
| | action is non-final. | | | | | |
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| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-31</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>1-3,5,6,9-12,14-16,18-23 and 26-31</u> is/are rejected. | | | | | | |
| 7) Claim(s) <u>4,7,8,17,24 and 25</u> is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or | r election requirement. | | | | | |
| Application Papers | | | | | | |
| | | | | | | |
| 9) The specification is objected to by the Examiner. 10) ☑ The drawing(s) filed on <u>26 September 2005</u> is/are: a) ☑ accepted or b) ☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a)⊠ All b)□ Some * c)□ None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
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| Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. | | | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 9/26/2005. 5) Notice of Informal Patent Application 6) Other: | | | | | | |
| Paper No(s)/Mail Date <u>9/26/2005</u> . 6) | | | | | | |

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DETAILED ACTION

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Election/Restrictions

Claims 32-34 are withdrawn from further consideration pursuant to 37 CFR
 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 6/7/2009.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 3. Claims 1, 2, 5, 9-12, 14, 29, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Bhatnagar et al. (Pub. No. US 2005/0080425 A1), which incorporates by reference applications 10/389,818 filed on March 18, 2003 and 60/365,026, filed on March 18, 2002.

Regarding claims 1, 2, 5, 9, 11, 12, 14, 29, and 30, Bhatnagar et al. discloses a device for distracting and supporting two' substantially opposing tissue surfaces in a patient's body (figure 9), to be introduced within the tissue surfaces in a minimally

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invasive procedure (claim 25), the device comprising: a wrapping dement 84 (figure 9); and an expandable structure 16 (figure 9) insertable between the two substantailly opposing support surfaces of the wrapping dement 84 (figure 9), adapted to be expanded between the two substantially opposing surfaces to a predetermined dimension (figure 9); paragraph 0059). The device is further provided with a conduit 44 (figure 8A), through which it is introduced into the patient's body. The wrapping element 84 comprises two substantially opposing support surfaces (figure 9). The expandable structure 16 comprises a plurality of beams 56, 58, 64 (figure 9). The expandable structure 16 comprises a segmented strip made of a series of jointed segments 56, 58, and 64 pivotally interconnected (figure 9) so as to present a multi-jointed strip (figure 9) each segment 56 and 58 having an elongated bore (illustrated in figure 9) provided on it through which a fastener may be interlaced, for holding the strip in a folded state of a desired height (fasteners connect actuation rod 46 to segments 56 and 58. The actuation rod holds the strip in a folded state of a desired height, figure 9). The expandable structure 16 is an initially squashed deployable polyhedron structure (figures 8A and 8B). The polyhedron structure has a cross section in the form of a parallelogram (figure 9). The expandable structure comprises two foldable straps 56/58/64 placed on either sides of a bar 46 (figure 9). The wrapping 84 is incorporated with the expandable structure 16 (paragraph 0059). The wrapping 84 is incorporated with an introduction device 44 used to introduce the device 16 to a target location (paragraph 0059). The expandable structure 16 is an initially collapsed deployable

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polyhedron structure (figures 8A and 8B). The polyhedron structure has a cross section in the form of a parallelogram (figure 8A).

Regarding claim 10, Bhatnagar et al. discloses a device for distracting and supporting two substantially opposing tissue surfaces in a patient's body (figure 8B), to be introduced within the tissue surfaces in a minimally invasive procedure (claim 25), the device comprising: a segmented strip made of a series of jointed segments 56 and 58 (figure 8B) pivotally interconnected so as to present a multi-joint strip (figure 8B), each segment 56 and 58 having an elongated bore provided on it (illustrated in figure 8B) through which a fastener may be interlaced, for holding the strip 56/58 in a folded state of a desired height (fasteners connect actuation rod 46 to segments 56 and 58. The actuation rod holds the strip in a folded state of a desired height, figure 8B).

4. Claims 1, 2, 5, 6, 23, 26-28, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumgartner (Pat. No. US 5,755,797).

Regarding claims 1, 2, 5, 6, 23, 26-28, and 31, Baumgartner discloses a device for distracting and supporting two substantially opposing tissue surfaces in a patient's body (figure 3), to be introduced within the tissue surfaces in a minimally invasive procedure (figure 3), the device comprising: a wrapping dement 10 (figure 3); and an expandable structure 7 (figure 3) insertable between the two substantially opposing support surfaces of the wrapping dement 10 (figure 3), adapted to be expanded between the two substantially opposing surfaces to a predetermined dimension (figure 9). The device is further provided with a conduit 6 (figure 3), through which it is introduced into the patient's body (col. 2, lines 60-67; figure 3). The wrapping element

10 comprises two substantially opposing support surfaces (figure 3). The two substantially opposing support surfaces are ragged on their internal surfaces (col. 2, lines 60-67 disclose that wrapping element 10 is a synthetic woven fabric. It is known to one skilled in the art that weaving a fabric results in a ragged texture). The expandable structure comprises a plurality of cylindrical elements 7 (col. 4, lines 66-67) that are linked loosely by a string 20 (figure 7) that can break up when the linked cylindrical elements 7 are pressed within the wrapping element 10 (functional language- the links 20 are capable of breaking upon the application of pressure due to their reduced diameter as shown in figure 7). The device is made of a plastic material (col. 1, line 66-col. 2, line 4 and col. 2, lines 60-67).

5. Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnson et al. (Pub. No. US 2002/0183761 A1).

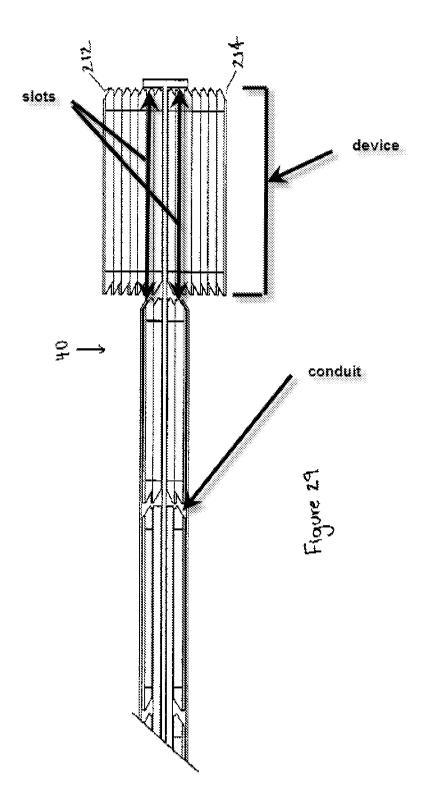
Regarding claims 1 and 3, Johnson et al. discloses a device (figure 29) for distracting and supporting two substantially opposing tissue surfaces in a patient's body, to be introduced within the tissue surfaces in a minimally invasive procedure, the device comprising: a wrapping element (paragraph 0177 "permeable membrane"); and an expandable structure "wafers" insertable between the two substantially opposing support surfaces of the wrapping element, adapted to be expanded between the two substantially opposing surfaces to a predetermined dimension (figure 29). The device is further provided with an introduction member 50 (figure 29), the introduction member 40 comprising a substantially linear conduit (figure 29), having a proximal end through which the device is inserted and a distal end where two substantially opposite slots are

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provided (figure 29), through which the expandable structure may protrude in directions substantially perpendicular to the conduit (figure 29).

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. Claims 1, 15, 16, 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner (Pat. No. US 5,171,280) in view of Bhatnagar et al. (Pub. No. US 2005/0080425 A1).

Regarding claims 1, 15, 16, 18-22, Baumgartner discloses a device (figure 7) for distracting and supporting two substantially opposing tissue surfaces in a patient's body, to be introduced within the tissue surfaces in a minimally invasive procedure, the device comprising: an expandable structure 2 (figure 6) insertable between the two opposing support surfaces of a wrapping element, adapted to be expanded between the two opposing surfaces to a predetermined dimension (figure 6). The expandable structure 2 comprises a coiled strap (figure 6) that is coiled over a rotor 10 (figure 6; col. 3, lines 56-67). The device further includes a propulsion belt 19 (figures 5 and 6; col. 4, lines 1-10) for driving the strap 2 and enhancing its coiling (col. 4, lines 1-10). The device is provided with a roller 15 for rolling the propulsion belt 19 (figure 6; col. 3, line 65 - col. 4, line 5). The belt 19 is provided with a ragged surface (glass fiber) for enhancing friction (col. 4, lines 1-5). The strap 2 is provided with a ragged surface in the region of numeral 7 (col. 3, lines 48-55, the ragged surface comprising a meshwork of PET threads).

However, Baumgartner does not disclose a wrapping element.

Bhatnagar et al. teaches a wrapping element 84 (figure 9) for the purpose of protecting the surrounding tissue from the working mechanism of the spreading assembly (paragraph 0058).

It would have been obvious to one skilled in the art at the time the invention was made to modify the distractor disclosed by Baumgartner to include a wrapping element for the purpose of protecting the surrounding tissue from the working mechanism of the spreading assembly, as taught by Bhatnagar et al. (paragraph 0058).

Allowable Subject Matter

8. Claims 4, 7, 8, 17, 24, and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached PTO form 892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYNNSY SCHNEIDER whose telephone number is (571)270-7856. The examiner can normally be reached on Monday - Friday, 9:30am-5pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. S./ Examiner, Art Unit 3733 /Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733